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An In Vitro Study of the Durability of a Proprietary Decalcification Inhibiting Sealant

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An *In Vitro* Study of the Durability of a Proprietary Decalcification Inhibiting Sealant

by

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the Requirements for the degree of
Master of Science in Orthodontics
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Each person whose signature appears below certifies that this thesis in their opinion is adequate, in scope and quality, as a thesis for the degree of Master of Science in Orthodontics.

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ABSTRACT

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Master of Science, Graduate Program in Orthodontics and Dentofacial Orthopedics
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Dr. Joseph Caruso, Chairperson

Plaque accumulation, although undesirable, is prevalent in orthodontic patients with poor oral hygiene and is linked with enamel decalcification. A proposed product designed to seal the tooth around the orthodontic bracket was tested for its durability. It also was evaluated for its ability to seal the enamel.

We measured prepared areas of sixty bovine teeth that were divided equally into two groups: a control group, protected with light-cured Concise sealant, and a group treated with the test sealant, Odyssey, both by 3M Unitek. The teeth were thermocycled for 1000 cycles in alternating 5° C and 55° C waterbaths at 10-second intervals each, in order to simulate the intra-oral environment temperature changes. This cycle time is equal to 5.5 hrs. of temperature change. The two groups were then separated into three 10-sample subgroups. Each subgroup was brushed with a different abrasivity toothpaste, for 400 cycles, using the V-8 Crossbrushing machine and Oral B 40 toothbrushes. This process simulated the equivalent of two weeks of toothbrushing (twice a day, five minutes total). The toothpastes used were a high abrasive commercially available dentifrice (Aquafresh – 160 rda), a medium abrasive commercially available dentifrice

(Crest – around 105 rda), and a low abrasive dentifrice (Rembrandt original – around 60 rda)

The amount of sealant left after abrasion was quantified using NIH Image software and then the percentage of sealant remaining on each tooth was calculated. Additionally, the remaining sealant thickness was evaluated microscopically by comparing Odyssey & Concise SEM photographs of select representative teeth from each sample.

Results are: Less of the Odyssey remained on the tooth (approximately 50%), after 2 weeks of simulated brushing compared to Concise (approximately 80% remaining.) There was no significant difference between toothpaste abrasivity (Low, Medium, or High) on wear of both Odyssey and Concise sealants. There were no statistically significant interactions between toothpaste and individual sealant. Under SEM there was no evidence of Odyssey remaining on the tooth surface.

INTRODUCTION

A common undesirable consequence of orthodontic treatment can be enamel demineralization seen as white spot lesions around the periphery of brackets and bands [1,2,4,6,10,11]. These lesions are primarily associated with poor oral hygiene, which is worsened because of the presence of orthodontic appliances, thus jeopardizing the patients' dental health by creating an increased risk of caries [1,2,3,4,5,7,9,14].

Although most of the pre-orthodontic treatment population may present with white spot lesions, post-treatment decalcification would be contrary to one of the objectives of orthodontics - contributing to an impaired esthetic result.

The purpose of this study was to determine the length of time that a proprietary sealant ("Odyssey") lasts on the natural tooth surface, since durability is critical to clinical success. To best approximate product behavior in the oral environment, thermocycling was conducted to simulate the temperature changes that restorations are submitted to. Toothbrushing was done to simulate a daily abrasive factor.

Early carious lesions present themselves as white spots of demineralized enamel which are direct results of acidic secretions from bacterial populations alive within plaque [1,2,3,5,6,7,10,11]. There are well-documented clinical observations and quantitative studies on incidence and prevention of decalcification in orthodontic literature [1,2,8]. Several studies suggest an equal incidence of white spot formation on bonded or banded teeth [3,4,6,10,11]. There is general consensus that decalcification associated with orthodontic appliances is directly related to the following: retention of plaque, especially on the gingival side of brackets and bands; oral hygiene practices; and an individual's inherent resistance [3,6]. Any compromise in oral health leads to an increase in plaque accumulation, an increase in total bacterial populations (especially *Streptococcus mutans* and *lactobacilli*), and inevitably an increase in caries susceptibility [4,5,9]. Enamel demineralization around bands and brackets can be alarmingly rapid; without any preventive therapies, visible white spot lesions may develop within 4 weeks, which can be the time of one appointment to the next[20].

Methods of protecting the enamel from decalcification include antibacterial varnishes, fluoride rinses, chlorohexidine mouthwashes, bonding agents (Protecto), fluoride-releasing elastomers[42], and chemical or light-cure orthodontic sealants to name a few. Each of these tested methods has its own strengths and shortcomings. Fluoride rinses and chlorohexidine mouthwash therapies have been shown to be effective in preventing demineralization. However, their level of success was found to be dependent and proportional to patient compliance, often a major problem.

Current enamel-protective methods include either the implementing of preventive cariostatic fluoride programs [1,2,5,14,18] or the use of different types of resin sealant on the enamel surface prior to orthodontic bracket bonding[7,8,12,13,15,16,17].

While fluoride can be effective, one study found that more than half of the patients studied were not compliant with the fluoride regimen instructed, thus reducing the potential positive effects [21,22]. Another concluded that resin sealants placed on tooth surfaces prior to bracket placement have too thin of a layer to offer abrasion resistance and do not protect the teeth long-term against demineralization. Even if the sealants are uniformly distributed on the enamel, improper curing due to oxygen inhibition makes the surface layer of the film to be lost[23]. While a low viscosity bond resin allows for better spreadability and resin penetration, it is also shown to produce inadequate film thickness necessary for protection against enamel demineralization[23]. There is a need to develop sealants that offer a durable and protective film to combat enamel demineralization contributed by orthodontic appliances[23].

An *in vitro* comparison of decalcification prevention effectiveness of teeth treated with Copalite, Portrait Veneer, a polymeric adhesive coating material (Protecto), and Nuva-Seal found that materials using the acid-etch technique such as Protecto and Nuva-Seal protected teeth against decalcification best. Nuva-Seal was the most effective, protecting teeth from decalcification for 21 weeks[24].

Testing by Banks & Richmond of a viscous chemically-cured sealant (Maximum Cure) versus a non-viscous visible light activated sealant (Transbond) led to the conclusion that Transbond provided no enamel protection, and Maximum Cure provided a significant but small reduction in post-debond decalcification[25]. An *in vitro* test was conducted to evaluate how etched, etched and remineralized enamel, and etched enamel impregnated with sealant (Estilux glaze) reacted after mechanical abrasion and acidic attack[41]. Their results showed that etched enamel, sealed or not, is weaker than untouched enamel but as long as resin tags were present in the enamel pits the sealant will prevent decalcification and caries, better than sound enamel, up to 2 years after placement of the resin[41]. Thus, depending upon the chemical constitution of the sealant, the film could actually seal and act in an interceptive and preventive way *in vitro*.

Some recent studies show that sealants on buccal and lingual surfaces of molars have less retention than those placed on occlusal sites, due to better mechanical interlocking[26]. Other recent studies indicate that sealants could provide an indirect protection on non-fissured surfaces[27].

Underwood et al. used a fluoride-exchanging resin as an orthodontic adhesive. They showed a 93% reduction in the first stages of enamel alteration demonstrating that fluoride-exchanging resin holds promise as a practical caries-preventive adhesive[28]. The majority of orthodontic sealants in use today are not fluoride-exchanging[29,30,31]. In addition, a most recent prospective study was performed *in vivo*, where white spot formation, gingival irritation, and plaque accumulation indexes were evaluated and compared between teeth sealed on the buccal areas around the bracket with a dual-cured lightly filled BIS-GMA fluoride-releasing sealant (Resilience M5 Protection Plus) and an untreated control. Results indicated no statistical difference on decalcification rates as well as no added benefit on gingival irritation and plaque accumulation between the sealed and unsealed control groups[43].

Rowland, et al. tested Odyssey, a proprietary product developed by 3M Unitek, to determine its efficacy as a coating for the reduction of *in vitro* plaque accumulation [19]. The findings, though promising, were not able to confirm that the product reduced plaque accumulation.

For any product to be effective it must show some, if not all of these characteristics: 1) Durability. 2) Non-toxicity. 3) Ease of use. 4) Cost effectiveness. 5) Decalcification reduction via inhibiting plaque accumulation, or 6) Decalcification reduction via another pathway.

Several seminal studies of dentifrice abrasivity have been conducted. One used the main four methods to study abrasion: laser light reflection, Radioactive Dentine

Abrasivity (RDA), surface profile measurements, and laser diffusometer measurements. Some noteworthy conclusions[32] include:

> "... [..]... when the abrasive particles are sufficiently small, the surface will reach the state where the roughness dimensions (i.e. scratches) approach the wavelength of the incident light, acquiring a smooth lustrous layer referred to as <polish>."

This confirms other established opinions[33]. Another conclusion is that the idea of an effective toothpaste may correspond to:

> "... [..]... the combination of abrasives of small and hard particles of aluminum silicate, with the softer and bigger particles of dicalcium phosphate dihydrate and calcium carbonate. The softer and bigger particles remove the soft film on the tooth surface with the small and hard particles subsequently taking care of the polishing."

Overall, though, their conclusion is that no single set of conditions will suffice for testing dentifrice abrasivity.[34]

A study by Harte et al. agrees with this conclusion, having evaluated abrasiveness by varying concentration, diluent, brush brand, brush hardness, and temperature of testing. Among their conclusions: hard brushes are more abrasive, glycerine as a diluent inhibited abrasion. Wear was shown to vary widely with concentration for the hard brush, but scarcely at all for the soft brush. A surprising discovery was that dentifrices became more than twice as abrasive as they were diluted from 100 to 50% abrasive component. Their hypothesis proposed that some component of the dentifrice limited abrasion until it was diluted. The findings of this study raised serious questions as to the validity of the ranking of dentifrice abrasiveness without regard to testing conditions[35].

An investigation of the difference in abrasiveness of 43 dentifrices concluded that there was a high degree of positive relationship between the weight loss caused by each dentifrice on human dentin as compared to that found on bovine dentin. A similar relationship was found between the combined weight loss and radiotracer techniques for measuring dentin abrasion. However, once again, the data demonstrated wide variations depending on testing conditions[36].

An analysis of pellicle-free enamel abrasion found a statistically significant difference of abrasion ($p<0.05$) between 500-10,000 strokes and 10,000-30,000 strokes. They observed a linear increase of abrasion only over 20,000 strokes. The sharp non-linear increase 0-10,000 strokes was presumed to be the effect of "hard" crystallites being preferentially removed from the soft organic matrix. Once that stage was passed, the organic matrix seemed to have determined abrasion behavior, hence the linearity[37].

During an investigation of toothbrushing abrasion of polyacid-modified composites in neutral and acidic buffer solutions, it was concluded that both Dyract and Compoglass suffered a significant reduction in abrasion resistance under acidic conditions[39].

Lastly, one study by May et al. evaluated the effect of a surface sealant on Class V restorations. Systems used were Dentin Conditioner + Fuji II LC; ProBond primer + VariGlass VLC; OptiBond + XRV Herculite; Scotchbond Multi-Purpose + Silux Plus; and Scotchbond Multi-Purpose + Restorative Z100. Half of the restorations in each group were randomly selected and sealed with Fortify resin. Specimens were thermocycled 500x (5 °– 55°C) and subjected to a silver nitrate microleakage test. Results indicated that application of the resin sealant significantly reduced leakage at the interface between VariGlass and dentin or cementum but had no effect on the other restorative systems[40].

As clearly demonstrated by all of the above, the rich tradition and established methodologies of abrasivity tests lend themselves naturally to investigating the durability of the orthodontic sealant "Odyssey" by 3M Unitek.

There is no doubt that reduction of decalcification during orthodontic therapy would be desirable, and total prevention of decalcification would be ideal. If plaque accumulation were reduced significantly, then these goals - along with reduced tissue inflammation - would be the result. An ideal product should not only seal the tooth, but also last long enough to effect a satisfactory prevention of decalcification. Clearly, the product of choice must bypass patient dental hygiene compliance and, up to this date, sealants are the only form of therapy that obviates the necessity of patient involvement [6,8,12,13,15,16].

The choice of conducting this experiment on bovine teeth instead of humans (for ease of procuring the samples) is supported by prior research which found no statistically significant differences between the microleakage behavior of human and bovine substrates. These results support the use of bovine teeth for *in vitro* studies[38].

The purpose of this study was to evaluate *in vitro* the amount of "Odyssey" sealant remaining on bovine teeth after thermocycling (to simulate the intra-oral temperature changes), and brushing with dentifrices of various abrasivities (high, medium, and low) to mimic possible daily wear factors.

METHODS AND MATERIALS

Freshly extracted bovine maxillary central and lateral incisors were used in this study. After extraction, the bovine teeth were preserved in de-ionized water. Each tooth was then mounted in an Additional Silicone block with the labial surface exposed and parallel to the block. The block was customized to hold the tooth firmly in the brushing machine. The mounted teeth were again stored in de-ionized water until ready for use.

A single researcher performed all the below experimental procedures. An initial pilot study was conducted to practice the even coating of the product on the specimens, and to minimize sealant thickness variability, as per manufacturer recommendation that only a single layer of the product be applied. In the pilot study, teeth were pumiced with WhipMix Grade Cl-60 Coarse, Louisville, KY, then etched for fifteen seconds with Ultra Etch 35% phosphoric acid, Ultradent Products, Inc, USA.. The prototype product Odyssey (a polymethacrylate unfilled resin) was packaged in a bottle requiring mixing prior to use. The cap of the bottle of Odyssey sealant was pressed allowing the activator to be expelled into the solution. The bottle was then shaken for one minute to allow for proper mixing of the elements. One layer of the sealant Odyssey, a proprietary product by 3M Unitek, Monrovia, CA, lot #118899/84, was painted on the tooth with a manufacturer-provided mini-brush. The sealant was then air-dried for a minimum of 20 seconds. After practicing sealant placement on twenty-two teeth, the researcher felt she was able to reproduce adequate uniformity of sealant layer thickness.

A second pilot study was conducted to determine the optimum number of toothbrush machine strokes for the experiment. Twenty-four mounted teeth were pumiced, etched and dried. Odyssey sealant was placed on the labial surface, as described above. The teeth were then divided into three groups of eight teeth each. One group was toothbrushed for 200 strokes, another for 400 strokes, and the third for 800 strokes. Results indicated that in the group cycled at the highest number of strokes (800) most of the Odyssey was abraded while in the group cycled at the lowest number of strokes (200) most of the product remained. Accordingly, in order to have a significant range of abrasion, the medium 400-stroke cycle was chosen for the experiment. This time is equivalent to approximately 2 weeks of toothbrushing (twice a day, five minutes total).

Two groups of 30 bovine incisors each were then selected. One group used the study sealant, Odyssey, and the other used the control sealant, Concise (a filled dimethacrylate resin), also by 3M Unitek, St. Paul, MN, lot #1930W. Each group was then divided into three 10-specimen sub-groups, for testing with different abrasivity toothpastes (high, medium and low abrasivity, respectively.)

A 4.0 mm diameter circle was created on the enamel of the labial surface of each tooth using a Micromite diamond drill by Lapgraft, Inc., Powell, OH. This delineated and standardized the surface test area (see Figure 1).

For the study, 60 teeth were pumiced, etched, and dried as described above, after which the sealants were applied to the two 30-sample groups. Odyssey was applied as per the pilot study. The control sealant, Concise, was applied on each tooth in one layer and light-cured with a 3M Unitek light held at 1-2 mm from the tooth surface for 20 seconds. All teeth were numbered for identification and stored at 40° C, in closed containers semi-filled but not submerged in water, for 96 hours.

Figure 1 - Mounted tooth in block, pre-staining. Note 4-mm diameter test area.

In order to simulate the intra-oral environment, all teeth were thermocycled for 1000 cycles at 10-second intervals each, at alternating 5° C and 55° C water baths. This cycle time is equal to 5.5 hrs. of intra-oral temperature change simulation (see Figure 2).

The two groups were then separated in three 10-sample subgroups. Each subgroup was brushed with a different abrasivity toothpaste, for 400 cycles, using the V-8 Crossbrushing machine, SABRI Dental Enterprises, IL, and soft Oral B 40 Straight toothbrushes, Oral B Laboratories, Belmont, CA. The toothpastes used were: a high abrasive commercially available dentifrice (Aquafresh, SmithKline-Beecham, Pittsburgh, PA – 160 rda), a medium abrasive commercially available dentifrice (Crest Fresh Mint Gel Tartar Protection, Procter & Gamble, Cincinnati, OH – cca. 105 rda), and a low abrasive dentifrice (Rembrandt Original, Den-Mat Co., Santa Maria, CA – cca. 60 rda.)

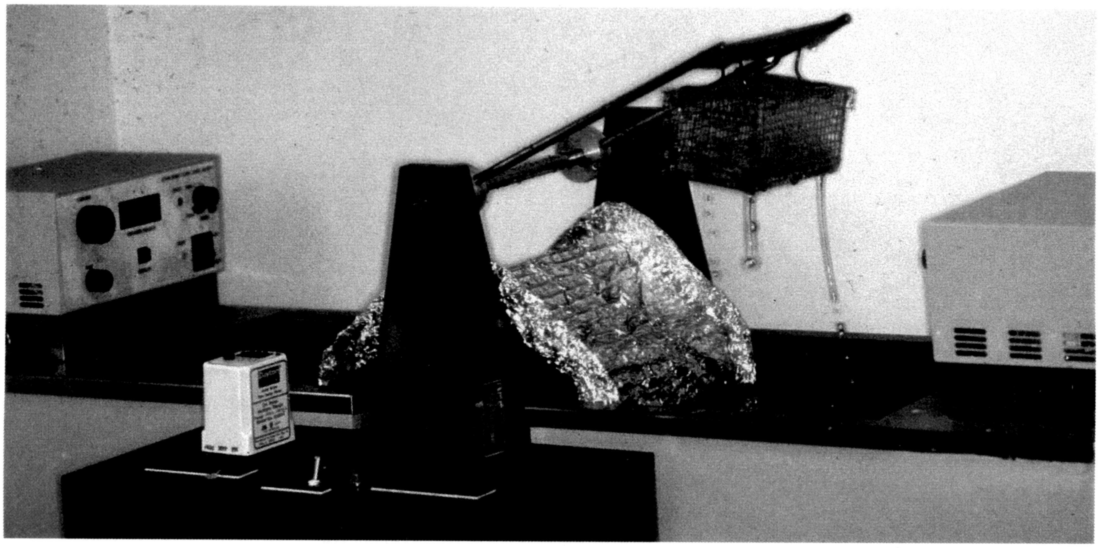

Figure 2 - Thermocycling machine, with hot/cold water baths.

A soft toothbrush was passed reciprocally over each sample which was mounted within a tube filled with the appropriate dentifrice slurry, composed of 25 grams of dentifrice and 40 ml of distilled water. The spring tension was adjusted to 150 grams as representative of toothbrushing force (Figure 3).

To evaluate the amount of sealant remaining, the labial surfaces of all teeth were acid-etched again with the same etching solution for fifteen seconds then rinsed thoroughly. Subsequently, they were immersed in a 2% aqueous solution of Acid Violet # 17, 3M Unitek, lot # 626574-4857, for 20 seconds then rinsed again. The exposed enamel stained purple, while the sealant-coated area remained white (Figure 4).

After staining, all teeth were digitally digitally photographed (Sony Digital Mavika Still Camera MVC-FD91 with 14X Optical Zoom Steady Shot, Sony, Japan) with a 52 mm close-up set (Quantanray,Japan), consisting of three lenses, +1, +2, and +4 diopters, that were used together for maximum magnification.

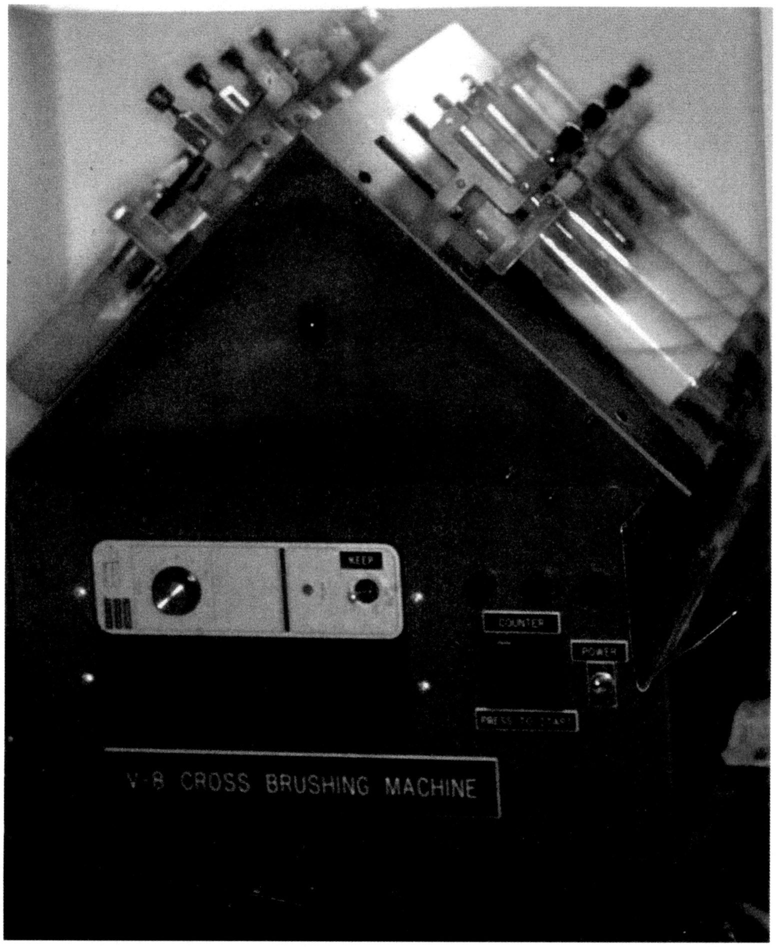

Figure 3 - Toothbrushing machine.

The distance between the tooth and lens was 144 mm which allowed for best focus. All photographs were taken in daylight with the same lens-to-tooth distance. The images were saved on PC-formatted diskettes and then transferred to a Macintosh computer. Each image was viewed in color using Photoshop software, version 4.0.

The percentage of sealant remaining on each tooth was analyzed using the software NIH IMAGE. Each photograph was individually opened in NIH IMAGE and displayed in grey-scale format (black&white). The whole image of the tooth and some of the block mold was visible. The software had an option that allowed delineation of any area of specific interest -- encoded as a circle on the upper left corner of the screen. That option was enabled and a circle was brought on the screen. The circle could be adjusted to be the appropriate dimension, which in this case it was measured to be 211x211 pixels (the same size circle was used for all teeth, since all teeth had identical test areas).

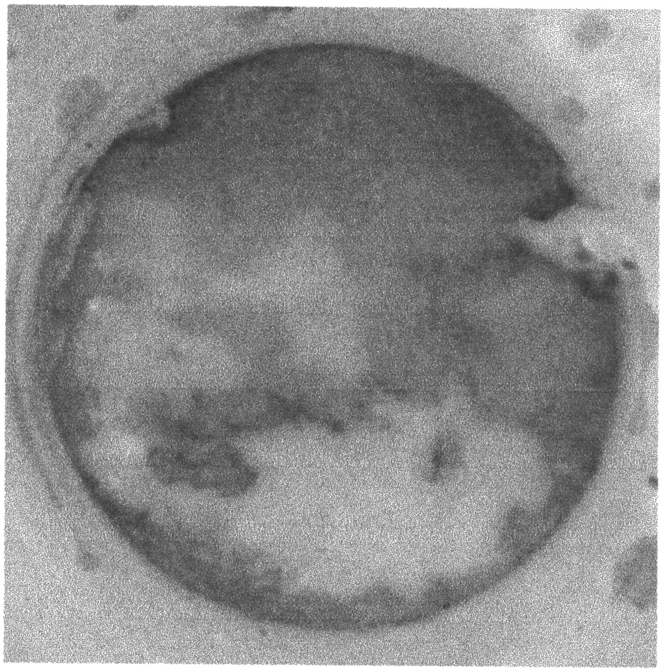

Figure 4 - Mounted tooth, post-staining.

This circle was dragged on to the desired portion of the photograph, which correspond to the 4mm diameter tooth test area. The delineated area (circle) was copied onto the clipboard. The folder was closed and a new folder was opened in the NIH image software. The copied circular image was then pasted on here, and sharpened. To double-check that the proper diameter had been selected (corresponding to 211 pixels), the total area of the circle was measured against the standard. The same photograph was subsequently opened in Photoshop and minimized to allow for color visualization of the tested circular area of the tooth only. The color Photoshop image was dragged to the side of the black&white, identical NIH image. The tool on NIH image was opened that allowed for the outlining of the non-abraded white area evident on the screen. The identical colored Photoshop image was used as a guide to clarify in NIH when the grey scale borders were too difficult to distinguish. The outlined area was then calculated. Microsoft Excel software was used to find the % of sealant remaining. The formula used was: % sealant remaining = (area sealant remaining / total area tested)x100.

After the first set of data was obtained the measurements were repeated and a second set of results were obtained. Each tooth was measured twice and two sets of measurements were taken in order to determine the operator's reliability in tracing.

Additionally, the sealant thickness remaining was evaluated microscopically by comparing Odyssey & Concise SEM photographs of select representative teeth from each sample. Three teeth were chosen, one from the control, one from the Odyssey group, and one tooth with no sealant. The teeth were sectioned inciso-gingivally, in the middle of the tested area with an Isomet low-speed saw, Buehler Ltd., IL, USA. One cut surface of both teeth was polished with a Metallographic polisher, Polimet 1, Buehler Ltd., IL, USA, using, first, a 600 Grit Carbimet Special Silicone Carbide Grinding Paper, Buehler, IL, USA, with a .05 micron Gamma Alumina paste, LECO, MI, USA, and then a Microcloth polishing cloth, Buehler, IL,USA. The cut surfaces were placed on an aluminium stand, facing up. The tooth was gold plated using HUMMER VII, ANATECH LTD., Alexandria, VA. The cut surface was then placed on the aluminum stand, facing horizontally. The sealant-enamel junction was qualitatively analyzed using a Scanning Electron Microscope, DSM 940, Zeiss, W.Germany.

RESULTS

The sealant wear-test results for Dentifrice 1 (high abrasivity), 2 (medium abrasivity) and 3 (low abrasivity) for the two groups (CONCISE, and Odyssey) were quantified and compared using a two-factor, ANOVA, parametric, fixed-effects model. Analysis showed that there is a statistically different treatment effect ($p<0.0001$), where Odyssey is less resistant to wear (approximately 50% remaining) than Concise (approximately 80% remaining), over a 2-week period of simulated toothbrushing (see Tables and Figures Section).

At a significance level of 5%, no statistically significant differences between toothpaste abrasivities were detected ($p=0.6124$) in either the Odyssey or the Concise group. In addition, there wasn't any statistically significant interaction effect between either Odyssey or Concise, and any of the toothpastes ($p=0.9149$).

In addition, a Kruskal-Wallis Ranks non-parametric test was undertaken which, again, confirmed that there were no statistically significant differences among the different toothpastes for Odyssey ($p=0.8590$), or CONCISE ($p=0.304$).

The percent of sealant remaining on the teeth was analyzed twice in order to establish the reliability of the experimenter. A high Intra-Correlation Coefficient (ICC) means that upon repetition of the experiment, the experimenter will be able to reproduce similar results with high likelihood. The higher the ICC, the more reliable the experimenter is in reproducing the results. In this study, the Intra-Correlation Coefficient was found to be 0.9229, indicating a high level of reproducibility (reliability) within the experimenter.

The two sets of data were analyzed; their relationship was identified and double checked using two distinct correlation coefficients: the Pearson's and the Spearman's correlation coefficients. The Pearson's correlation coefficient measures a linear relationship and assumes normality while Spearman's coefficient is based on ranks of the measurements and it does not assume normality. Pearson's correlation coefficient was $r=0.9248$, while Spearman's correlation coefficient was $\rho=0.9246$. Both are high and indicate a good degree of experimental reproducibility between the two sets of determined sealant-remaining areas.

Additionally, the SEM photographs qualitatively show that the amount of Odyssey sealant remaining post-testing is negligible, compared to Concise. The Concise tooth shows an obvious layer of sealant, whereas the Odyssey tooth looks identical with the un-sealed tooth, showing no sealant remaining (Figure 5.1, 5.2 and 5.3).

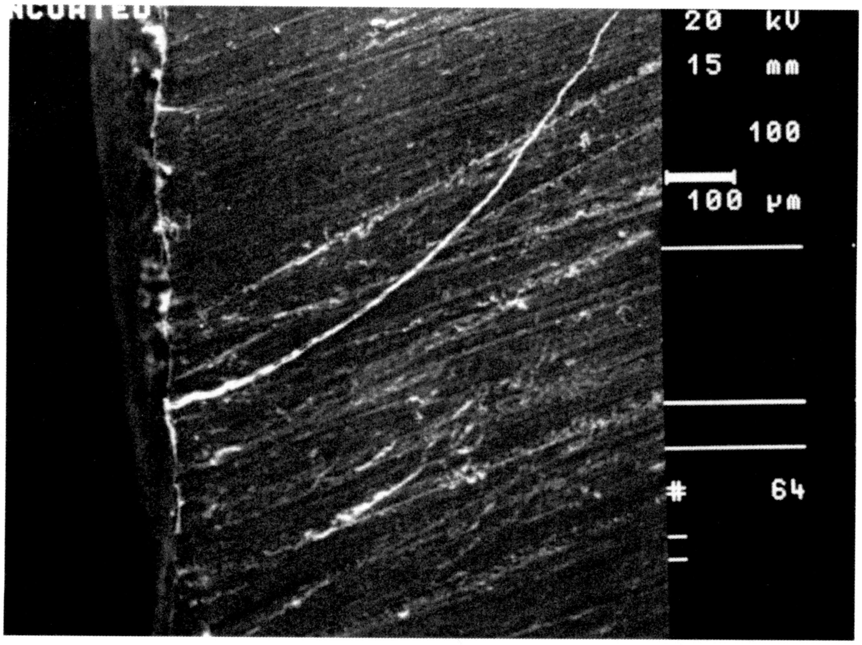

Figure 5.1 Uncoated tooth. Blurry area on left is the enamel surface.

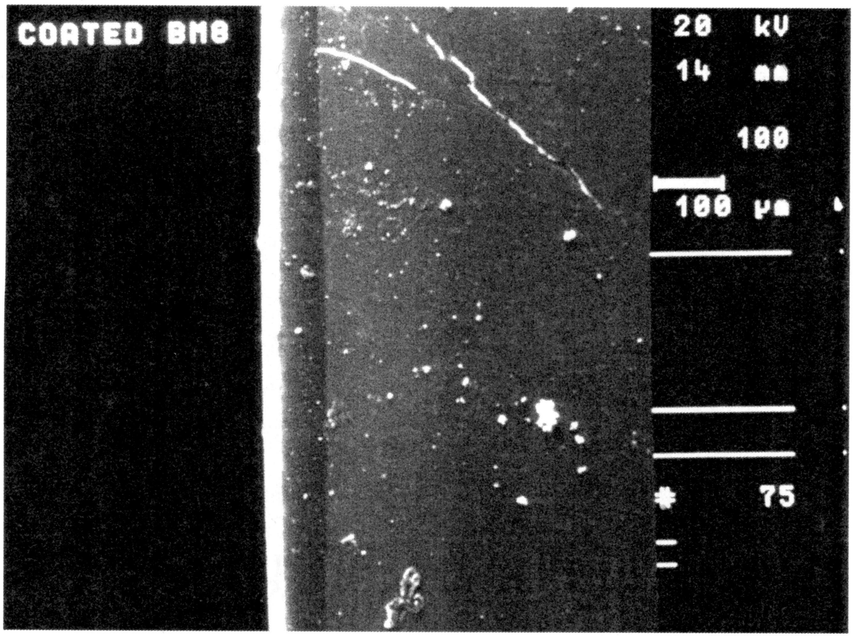

Figure 5.2 Tooth coated with Concise. Notice the sealant layer on the left.

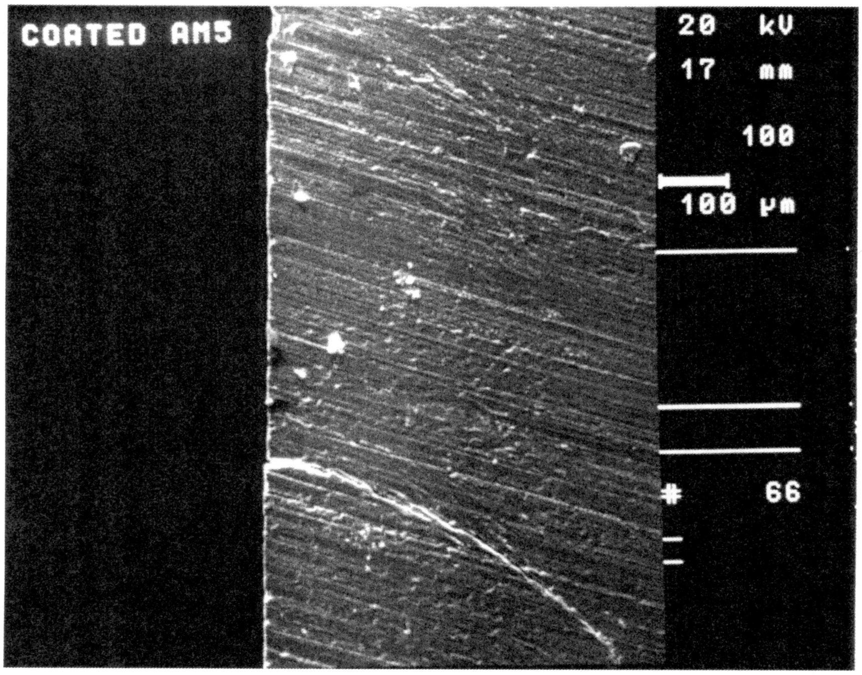

Figure 5.3 Tooth coated with Odyssey. Notice lack of remaining sealant.

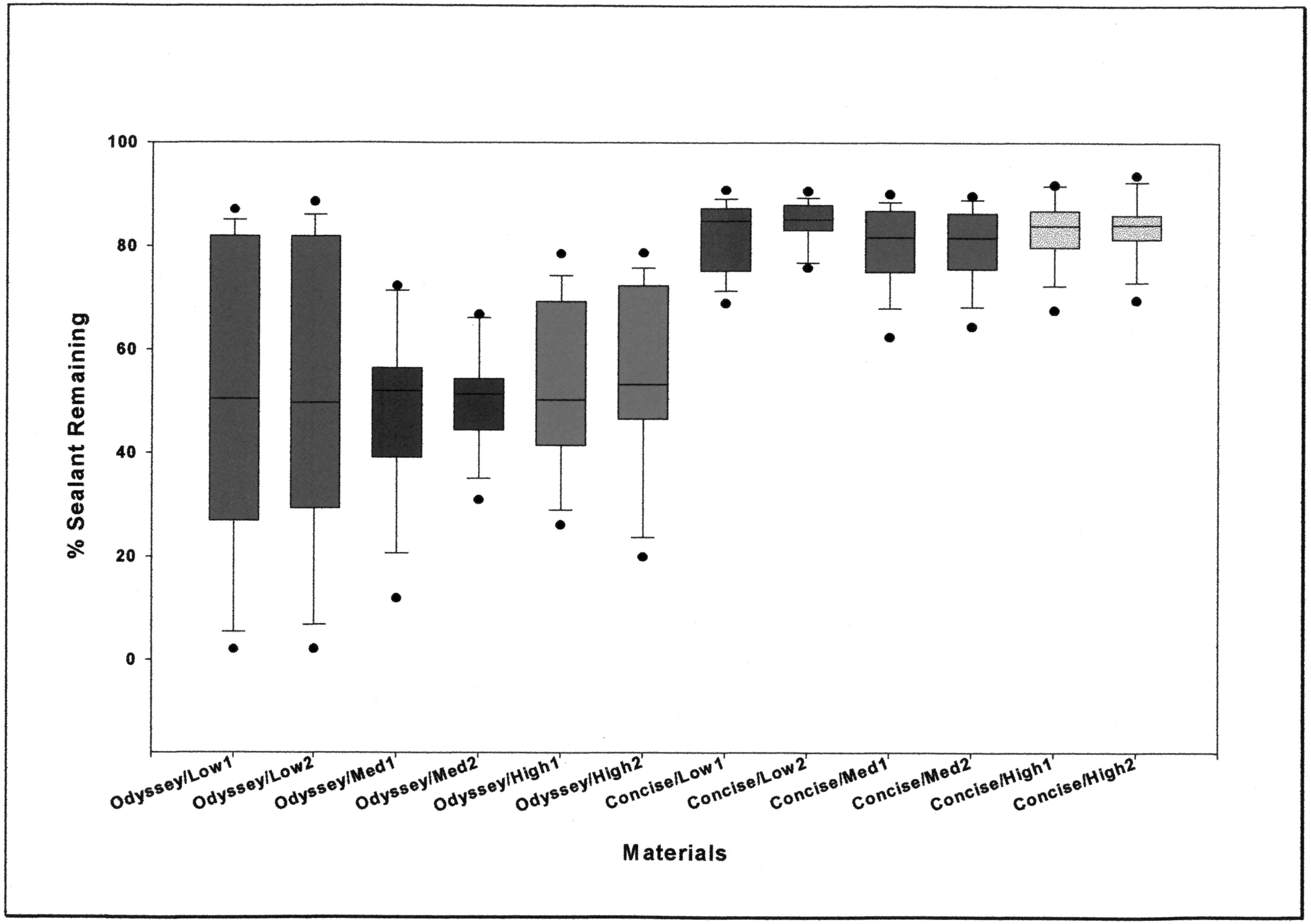

Figure 6.1 Percent of Sealant Remaining for Odyssey and Concise for the Two Measurements Taken.
(Box=Middle 50% of Data , Bottom Box Line=25th Percentile, Line within Box=Median, Top Box Line=75th Percentile, Filled Circle=Outlier)

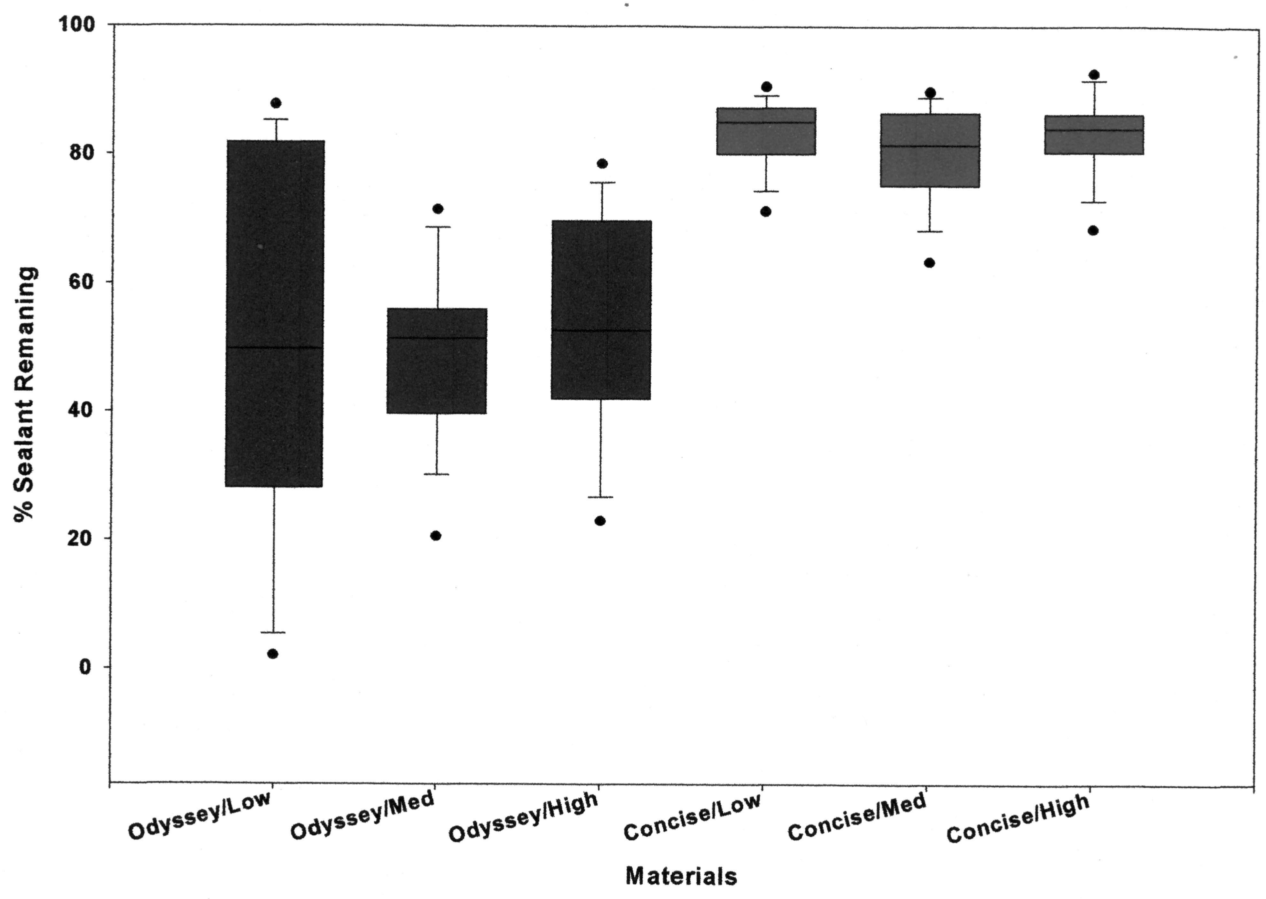

Figure 6.2 Percent of Sealant Remaining for Odyssey and Concise for the Mean Combined Measurements.
(Box=Middle 50% of Data , Bottom Box Line=25th Percentile, Line within Box=Median, Top Box Line=75th Percentile, Filled Circle=Outlier)

Table 1.1 - Percent Sealant Remaining for Odyssey and Concise for First Set of Measurements

	Odyssey/Low	Odyssey/Med	Odyssey/High	Concise/Low	Concise/Med	Concise/High
Mean	49.24	47.95	52.37	82.18	80.28	82.96
Median	50.45	52.02	50.23	84.87	81.7	83.94
Mode	2.04	11.87	26.07	68.94	62.45	67.62
SD	30.43	18.50	17.60	7.09	8.29	7.09
CV	0.62	0.39	0.34	0.09	0.10	0.09
Minimum	2.04	11.87	26.07	68.94	62.45	67.62
Maximum	87.06	72.4	78.53	90.85	90.07	91.8

n = 10

Table 1.2 - Statistical Difference Between Toothpastes and Sealant Type for the First Set of Measurements

	Mean	SD	CV
Odyssey/Low	49.24	30.43	0.62
Odyssey/Med	47.95	18.50	0.39
Odyssey/High	52.37	17.60	0.34
Concise/Low	82.18	7.09	0.09
Concise/Med	80.28	8.29	0.1
Concise/High	82.96	7.09	0.09

n = 10

Groups connected by vertical lines are not statistically different at P> 0.05

Table 2.1 - Percent Sealant Remaining of Odyssey and Concise for the Second Set of Measurements

	Odyssey/Low	Odyssey/Med	Odyssey/High	Concise/Low	Concise/Med	Concise/High
Mean	51.42	50.38	53.37	84.55	80.33	83.33
Median	49.73	51.4	53.25	85.16	81.62	84.14
Mode	2.07	30.95	19.93	75.86	64.5	69.58
SD	30.11	11.00	19.19	4.61	8.00	6.82
CV	0.59	0.22	0.36	0.06	0.1	0.08
Minimum	2.07	30.95	19.93	75.86	64.5	69.58
Maximum	88.56	66.83	78.73	90.59	89.69	93.64

n = 10

Table 2.2 - Statistical Difference Between Toothpastes and Sealant Type for the Second Measurement Set

	Mean	SD	CV
Odyssey/Low	51.42	30.11	0.59
Odyssey/Med	50.38	11.00	0.22
Odyssey/High	53.37	19.19	0.36
Concise/Low	84.55	4.61	0.06
Concise/Med	80.33	8.00	0.1
Concise/High	80.33	6.82	0.08

n = 10

Groups connected by vertical lines are not statistically different at P> 0.05

Table 3.1 - Mean Percent Sealant Remaining Using the Combined First and Second Sets of Measurements

	Odyssey/Low	Odyssey/Med	Odyssey/High	Concise/Low	Concise/Med	Concise/High
Mean	50.33	49.16	52.87	83.36	80.30	83.14
Median	49.73	51.4	52.87	83.36	80.3	83.14
Mode	2.04	11.87	19.93	68.94	62.45	67.62
SD	29.48	14.86	17.92	5.95	7.93	6.77
CV	0.59	0.3	0.34	0.07	0.1	0.08
Minimum	2.04	11.87	19.93	68.94	62.45	67.62
Maximum	87.06	88.56	72.40.78.73	90.85	90.07	93.64

n = 10

Table 3.2 - Mean Statistical Difference of the Combined First and Second Measurement Sets Between Toothpastes and Sealant Type

	Mean	SD	CV
Odyssey/Low	50.33	29.48	0.59
Odyssey/Med	49.16	14.86	0.3
Odyssey/High	52.87	17.92	0.34
Concise/Low	83.36	5.95	0.07
Concise/Med	80.30	7.93	0.1
Concise/High	83.14	6.77	0.08

n = 10

Groups connected by vertical lines are not statistically different at $P > 0.05$

Table 4 - List of Materials

Material	Supplier	Lot #
Odyssey Sealant	3M Unitek, Monrovia, CA	11899/84
Concise Sealant	3M Unitek, St. Paul, MN	193 OW
2% aquaeous solution (Acid Violet #17)	3M Unitek, Monrovia, CA	626574-4857
Aquafresh Toothpaste	SmithKline-Beecham, Pittsburgh, PA	(L)9H16
Crest Fresh Mint Gel Tartar Protection Toothpaste	Procter & Gamble, Cincinnati, OH	923909
Rembrandt Tothpaste	Den-Mat Co., Santa Maria, CA	155

DISCUSSION

The purpose of this study was to evaluate *in vitro* the amount of sealant remaining on bovine teeth after thermocycling, to simulate the intra-oral temperature changes, and brushing with dentifrices of various abrasivities (high, medium, and low) to mimic possible daily wear factors. In order for this product to fight decalcification around brackets, it must be able to remain on the tooth for a reasonable amount of time. This would have been most cost-effective, since it would have provided the optimum inter-appointment time-frame for re-application.

Tests have been performed to determine this product's ability to reduce *in vitro* plaque accumulation. Since no data was available to determine the longevity of this product on a tooth, an *in vitro* study simulating the intra-oral environment and daily wear was necessary, before any *in vivo* testing could be justified. If the *in vitro* test showed the product to last an acceptable amount of time, appropriate enough to warrant its use on orthodontic patients, then an *in vivo* study would be acceptable to confirm the results. If, however, the *in vitro* study showed the product not to last on the tooth an amount of time feasable for orthodontic whitespot lesion prevention, then further *in vivo* studies would be futile until the product would be improved to merit futher examination.

Thus, this study was a preliminary *in vitro* data-gathering experiment to see how Odyssey, a proprietary product, compares with a known product Concise in retention on a tooth under a simulated oral environment for the equivalent of two weeks of toothbrushing with different abrasivity toothpastes.

The results of the study show that the Odyssey sealant is not as successful as Concise in being retained on teeth that underwent thermocycling and the 2 week-equivalent of toothbrushing simulation. This means that most likely Odyssey will be equally unsuccessful intra-orally, and it does not merit further *in vivo* investigation with its present properties.

One possible reason why Odyssey performed poorer than Concise is that after placement, the Odyssey layer was significantly thinner than the Concise layer. This may be due to the presence of silica particles in the Concise sealant, as filler, which make Concise more wear-resistant than Odyssey, which is unfilled. The above-mentioned explains the SEM qualitative results, showing Concise as being much more durable than Odyssey.

Perhaps if the manufacturer increased the thickness of the now-recommended single-application layer of the product, then the Odyssey may respond as well as, or even better than the Concise sealant. Another way yet is for the manufacturer to devise a way to allow the Odyssey sealant to be placed initially in multiple layers, rather than the single layer which is presently recommended (currently multiple layers do not adhere cohesively). In addition, there could be a bonding difference between Concise, which may penetrate the enamel better than the Odyssey sealant. So far, only approximately 50% of this proprietary sealant remains after two weeks of toothbrushing and intra-oral simulation. As is now, the product would probably have to be placed weekly, in order to be beneficial as a decalcification preventative method.

Thus, as the product stands now it cannot be recommended for orthodontic patient use as a means of prevention against white spot lesions. More work needs to be done in order to improve this proprietary material, before it can be of any use on the market as an orthodontic decalcification prevention tool.

CONCLUSIONS

1) Less of the Odyssey remained on the tooth (approximately 50%) than Concise (approximately 80%) after an *in vitro*, intra-oral thermal simulation equivalent to 2 weeks of toothbrushing.
2) There is no significant difference between toothpaste abrasivity (Low, Medium, or High) on wear of either Odyssey or Concise sealants.
3) There is no statistical significant interaction between toothpaste and individual sealant.
4) Under the SEM there was no evidence of Odyssey remaining on the tooth surface.

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